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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,387	11/29/2005	Dan Pitulia	43318-225722	5702
26694	7590	10/15/2007	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998				PENDLETON, DIONNE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/558,387	PITULIA, DAN	
	Examiner Dionne H. Pendleton	Art Unit 2627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 July 2007.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 9-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 9-11 and 13-21 is/are rejected.
- 7) Claim(s) 12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Priority***

1. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “**machine driver**” of claim 13, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "machine driver" in claim 13.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 15** recites the limitation "the plastic package" in line 4. There is insufficient antecedent basis for this limitation in the claim.

*Claims 16-21 are also rejected due to claim dependency.*

*For the sake of further expediting prosecution of the claim, the recitation of "plastic" has been treated as if the Applicant intended to recite "sterile".*

5. **Claims 16-21** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 1 of Claim 16 recites, "the package comprises...". Is the Applicant referring to the "sterile package" or the "titanium packaging"?

*Claims 17-21 are rejected due to claim dependency.*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 9-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakansson (US Patent No. 6,840,919) in view of Carlsson et al. (US 6,599,97).**

**Regarding claim 9,**

Hakansson teaches an implant device for bone anchored hearing aids comprising a pre-mounted unit (*column 10, lines 26-32*) comprising a screw-shaped anchoring fixture ("24" in figure 2) configured to be anchored in bone tissue (1); an abutment sleeve (11) configured to penetrate skin (2) and comprising a tool engaging portion ("14" in figure 3), and a screw connecting the abutment sleeve to the fixture (see *column 9, lines 15-18*); and

a tool (*inherently required*) configured to install the entire pre-mount unit into the bone tissue wherein the tool is configured to cooperate with the tool engaging portion ("14" in figure 3) of the abutment sleeve when installing the implant into the bone tissue (1).

Hakansson teaches a that the pre-mount unit is anchored in bone tissue using a plurality of arms(12). Since a screw member(4) is provided into each arm(12) for anchoring to bone tissue, Hakansson does not teach that the pre-mount unit is installed in one step.

Carlsson teaches a device ("1" in figure 1) for anchoring into bone tissue, wherein the device is similar in shape to that of the abutment sleeve (11) of Hakansson, and further wherein the front portion (2) of the device is provided with a threaded portion with cutting edges (4) in order to permit self-tapping/scrapping anchorage into the bone tissue, wherein the device may be anchored into the bone tissue in "one step", as recited in the claim (see *column 3, lines 43-48*).

It would have been obvious for one of ordinary skill in the art at the time of the invention to substitute the threaded bone anchorage configuration of Carlsson, for the arm-attachment anchorage configuration of Hakansson, for the purpose of providing a single step method for anchoring the device within the bone of the user, requiring fewer tools and less time.

**Regarding claim 10,**

In column 6, lines 58-60, **Hakansson** teaches the need for a flange-like structure to separating the bone penetrating portion of the device from the non-bone penetrating portion of the device, thus corresponding to "a flange operative as a stop". While, **Carlsson** teaches self-tapping edges (4) provided on the front of the device.

**Regarding claim 11,**

Hakansson teaches that the tool engaging portion (14) of the abutment sleeve (11) comprises a plurality of symmetrically arranged recesses or holes ("15" in figure 3; *also see the "recess" which is provided under the upper lip and which is more clearly shown in figure 9*).

**Regarding claim 13,**

Hakansson's device inherently requires a tool for installing the implant device, wherein such tool would include a second part for manual insertion of the implant device, as claimed. *With consideration to objection to the Specification above*, Hakansson appears to teach that the tool would comprise a first part for engaging a "machine driver".

**Regarding claim 14,**

Hakansson's device inherently requires a tool for positioning the disclosed implant device within the skull of a person. Hakansson does not clearly teach a tool specifically constructed as claimed, including a resilient ring for cooperating with an edge of the abutment sleeve to provide a lifting function. However, the Examiner takes *Official Notice* that special driver tools for manual insertion of an implant device are well known in the art and would have been obvious provide a tool specifically constructed for mating engagement with the abutment sleeve of Hakansson for the

purpose of securely retaining the implant device thereon during placement into the bony tissue of patients.

7. **Claims 15-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hakansson (US Patent No. 6,840,919)** in view of **Carlsson et al. (US 6,599,97)** as applied to claim 14 above, and further in view of **Branemark (US 4,712,681)**.

**Regarding claim 15,**

**Hakansson and Carlsson** teach the implant device according to claim 14. **Hakansson and Carlsson** fail to teach a sterile package and titanium package, as specifically claimed.

**Branemark** teaches a method for packaging in implant device comprising a sterile package ("6" in figure 2) to contain the implant device; as well as a titanium packaging sleeve ("1" in figure 1) for retaining the implant device ("4" in figure 1) in a preferred position, wherein after opening the *sterile* package (*as best understood with regard to the USC 112 second paragraph rejection above*), the implant device is configured to be separated from the titanium packaging sleeve (1) with the tool and lifting function, as is well known in the art.

It would have been obvious for one of ordinary skill in the art at the time of the invention to package the implant device of **Hakansson and Carlsson**, into a sterile packaging arrangement, as taught by **Branemark**, for the purpose of storing the implant device in a contamination free manner.

**Regarding claim 16,**

*As best understood with regard to the USC 112 second paragraph rejection above, and in Figure 1, Branemark teaches that the package comprises a package portion (2) and lid portion (3). Branemark fails to teach that the package comprises a sealing ring between the package portion and lid portion. However, in column 2, lines 60-64, Branemark recognizes a need in the art for providing a vacuum-tight sealing between the package portion (2) and lid portion (3).*

It would have been obvious for one of ordinary skill in the art at the time of the invention to utilize any reasonable variety of elements such as a "sealing ring", for providing a vacuum tight sealing between the package body and lid portion, for the purpose of preventing any possible impurities from reaching the implant device, located inside.

**Regarding claim 17,**

**Hakansson and Carlsson** teach the implant device according to claim 16. Hakansson and Carlsson fail to teach that the package is made of plastic. However, the Examiner takes *Official Notice*, that sterile plastic-packaging is well known in the art and would have been obvious to use as an alternative to sterile metal foil-packaging since sterile plastic-packaging may be transparent, thereby making it's contents easily identifiable, and it also would have been obvious to use as an alternative to sterile-glass packaging since the sterile-plastic is more durable and resists breakage from mishandling.

**Regarding claim 18,**

In Figure 1, Branemark teaches that the package (2) comprises a cylindrical outer surface.

**Regarding claim 19,**

*As best understood with regard to the USC 112 second paragraph rejection*  
above, the teachings of Branemark combined with that which is obvious in the art for providing a sealed connection, appears to teach a sealing ring arranged on the outer surface of the package.

**Regarding claim 20,**

In Figure 1, Branemark teaches that the package portion (2) and lid portion (3) comprise a screw connection (shown).

**Regarding claim 21,**

*As best understood with regard to the USC 112 second paragraph rejection*  
above, the teachings of Branemark combined with that which is obvious in the art for providing a sealed connection, appears to teach a sealing ring adjustable in a longitudinal direction.

***Allowable Subject Matter***

8. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne H. Pendleton whose telephone number is 571-272-7497. The examiner can normally be reached on 10:30-7:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wayne Young can be reached on 571-272-7582. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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